



## OFFICE OF THE SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

FEB 17 1994

MEMORANDUM TO DIRECTORS OF THE DEFENSE AGENCIES

SUBJECT: Protection of Human Subjects in Research

On August 11, 1991, the Federal Common Policy for the Protection of Human Subjects in Research was adopted by the Department of Defense (DoD) and published in Title 32, Code of Federal Regulations, Part 219. Subsequently, Policy Guidance for implementation of the Human Subjects Regulations was issued jointly on June 10, 1993 by the Assistant Secretary of Defense (Health Affairs) and the Office of the Director, Defense Research and Engineering to the Assistant Secretaries of the Military Departments having cognizance for research, development, testing, and acquisition.

It has been brought to our attention that at least one Defense Agency has recently initiated a program in medical technology. To ensure that all Department of Defense Agencies are in compliance with current human use regulations, it is requested that each Director indicate whether his Agency conducts or provides funding support for intramural or extramural research which involves human subject participation. If an Agency does conduct or support human subjects research the required administrative package will be provided to ensure Agency compliance with the above Federal Regulation. For clarity, research is defined as a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Human subjects is defined as a living individual about whom an investigator (professional or student) conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information regarding the individual used for research purposes.

Directors are requested to provide the status of Agency participation in the conduct or support of intramural or extramural human subject research by March 4, 1994 to

Director, Environmental and Life Sciences  
Office of the Director, Defense Research and Engineering  
Pentagon Room 3D129  
Washington, D.C., 20301-3030

Negative responses are required.

My point of contact for this action is Captain John F. Jemionek, MSC, USN, who may be contacted at (703) 697-1494. Your assistance in ensuring total DoD compliance with Federal Regulation in the area of human subject protection in research is appreciated.

*Edward D. Martin*

Edward D. Martin, M.D.  
Acting Assistant Secretary  
of Defense (Health Affairs)

*Joseph V. Osterman*

Joseph V. Osterman  
Director, Environmental  
and Life Sciences

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ROUTE TO		ACTION	SIGNATURE (Grade and Surname)	ORIGINATOR (Symbol)	TELEPHONE NO	DATE
1	PAG	Review		PAG-TA		SG1B 14 Mar
2	PA	Coord				
3	PC	Sign SSS				
4	ESO					
5	GC					
6	CS					
7	DD					
8	DR	Sign Ltr				

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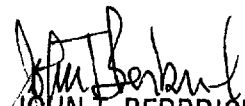
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SG1J

SUBJECT

Protection of Human Subjects in Research (U)

REMARKS

1. (C/NF) PURPOSE: To provide the status of DIA's participation in the conduct or support of intramural or extramural human subject research.
2. (U) BACKGROUND: The memorandum opposite provides the DIA response to requirements set forth in ESO tasker #710.
3. (U) DISCUSSION:
  - a. (S/NF) DIA has determined that only one program (Project STAR GATE) falls within the definition of human subject research. This research is conducted in two areas: in-house activities conducted by DIA civilian personnel and external research activities conducted under DIA contract with the Science Applications International Corporation (SAIC).
  - b. (S/NF) Both the DIA and DoD General Counsels have determined that the STAR GATE Project constitutes experimentation on human subjects. As required by Procedure 13 of DoD Directive 5240.1-R, approval for project activities has been granted by the Deputy Secretary of Defense. DIA personnel involved with in-house investigations are required to sign a Statement of Consent form approved by the DIA General Counsel. External research conducted by SAIC is in full compliance with all applicable laws, Federal regulations and DoD instructions.
  - c. (S/NF) This matter was coordinated throughout all of DIA, and no other programs were determined to fall within the definition of human subject research.
4. (U) RECOMMENDATION: Request the Director sign the memorandum opposite.

  
JOHN T. BERBRICH  
Director  
National Military Intelligence  
Production Center

1 Enclosure  
OSD Memorandum,  
dtd 17 Feb 94, sab (U)

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